REMARKS

In the Final Office Action under reply, claims 1-4, 6-8, 12, 13, 26, 29, 46, 47, 101, 102, and 104-109 stand rejected. Claims 9-11 and 14-22 stand withdrawn as directed to nonelected species and claim 76 stands withdrawn as directed to a nonelected invention.

With this response, claim 1 is amended, and non-elected claim 76 is canceled. Accordingly, upon entry of this amendment, claims 1-4, 6-22, 26, 29, 46, 47, 101, 102, and 104-109 will remain pending.

Applicants acknowledge with appreciation the withdrawal of the grounds for rejection and/or objection from the previous Office Action.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and have not acquiesced to any rejections or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution on any presently excluded subject matter in one or more future continuation and/or divisional application(s).

Reconsideration is respectfully requested in light of the above amendments and the following remarks. For the Examiner's convenience, Applicants' remarks are presented in the same order in which they were raised in the Office Action.

A. November 2, 2010 Telephone Interview Summary

Applicants wish to thank Examiner Lezah Roberts and Examiner Jeffrey Lundgren for taking the time to conduct a telephone interview on November 2, 2010 with the attorney of record, Shantanu Basu, the inventors on this application: Dr. Jerry Gin and Benjamin Ross, and Bolko Stolberg, representative of the assignee. All issues set forth in the Office Action under reply were discussed, including the art rejections.

Applicants express their appreciation for the Examiner's helpful suggestions regarding the use of the term "constituents of essential oils" in the claims and possible amendments to overcome issues raised by the claim language.

This response is submitted pursuant to that discussion.

B. Amendments to the claims

During the course of the telephone interview on November 2, 2010, the Examiner advised Applicants that recitation of the term "a flavoring agent selected from essential oils, constituents of essential oils, and mixtures thereof, the flavoring agent representing approximately 25 wt. % to 49.5 wt. % of the lozenge" in claim 1, implied that the recited weight percentage applied not only to the essential oil but would include "constituents of essential oils" in calculation of the weight percentage and thus the Friedman reference (WO 99/06030) was applied to reject the claims.

In response, Applicants amend claim 1 to clarify that the essential oil itself represents "approximately 25 wt. % to 49.5 wt. % of the lozenge." Claim 1(b), as amended, now recites: "a flavoring agent comprising essential oils, and optionally, constituents of essential oils, the essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge."

Support for the amendment can be found at paragraph 0041 (page 14) of the Specification. ("Ideal flavoring agents in this regards are pharmaceutically acceptable essential oils and chemical constituents of essential oils that can impart a desired flavor"). Paragraph 0042 lists a number of essential oils that can be incorporated as suitable flavoring agents. Paragraph 0043 provides examples of constituents of essential oils. Several examples disclosed at paragraphs 0097 *et seq,* of the Specification describe lozenges according to the invention that include peppermint oil, or orange oil as instances of "essential oils" without any "constituents of essential oils" included in the disclosed formulations.

The amendment is presented for clarity and no new matter is added.

Applicants submit that the amendment places the claims in condition for allowance and/or in better condition for appeal. The amendment is necessary to clarify the claim language with respect to the cited art and is being presented at this time after being advised by the Examiner that the pre-amendment claim language was unintentionally reading on the cited art.

Applicants believe that the amendments do not raise new issues, do not require any further consideration or search by the Examiner, and overcome all grounds of final rejection. Entry of the after-Final amendments under 37 CFR §1.116 is respectfully requested.

C. Request to Reconsider Finality of Rejection

The Examiner has designated the current Office Action as Final.

All art cited in support of the only ground for rejection (obviousness over Friedman, Lin, Gohlke and Ventouras) have been cited previously.

The only amendments to independent claim 1 submitted in response to the First Office Action, addressed indefiniteness issues and specified that the recited weight percentages of the ethyl cellulose or flavoring agent were relative to the lozenge. The extended time period was defined to be between 15 minutes and 4 hours.

Applicants submit that their amendments submitted in response to the prior Office Action, did not make Friedman any more relevant to the claim language. The Examiner has stated that the limitation "constituents of essential oils" necessitated application of the Friedman reference towards the rejection. The term in question was already in the claims pending prior to the First Office Action.

Therefore, Applicants believe that they should be entitled to file another response before finality is applied to the prosecution of the pending claims. In light of the urgency of getting allowable claims as Applicants' products covered by the claims are already on the market, Applicants believe that withdrawal of finality will expedite prosecution and avoid any need for filing additional Requests for Continued Examination. Further, Applicants believe that all issues remaining in regard to placing the claims in allowable form are addressed by this amendment.

Reconsideration of the Final status of the outstanding Office Action is respectfully requested.

D. Claim Rejections – 35 U.S.C. §103 (obviousness)

(i) Claims 1-4, 6-8, 12, 13, 26, 46, 47 and 102-109 stand rejected under 35 USC 102(b) as being obvious under 35 USC 103(a) over Friedman *et al.* (WO 99/06030) in view of Lin *et al.* (J. Controlled Release 2001) and Gohlke (US 2002/0054917), all references being previously of record.

The primary reference Friedman is cited to describe a sustained release lozenge that contains ethyl cellulose matrix and contains essential oils and herbal extracts. The Examiner alleges that the limitation of essential oils and herbal extracts, which Friedman describes to be between 0.5 to about 40% by weight corresponds to the limitation "essential oils, constituents of essential oils, and mixtures thereof, … representing approximately 25 wt. % to 49.5 wt. % of the lozenge," as recited in the previously pending claims.

The secondary references, Lin and Gohlke, are cited as pertaining to disclosing the effects of ethylcellulose powders on release rate of drugs, and lozenges chewable for prolonged periods of time, respectively.

In response, Applicants amend the relevant section of independent claim 1 to specify: "a flavoring agent comprising essential oils, and optionally, constituents of essential oils, the essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge."

Applicants submit that none of the cited art teach or suggest the limitation of: "essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge."

Friedman discloses at page 6, lines 7-9, that "[t]he essential oil and herbal extract are preferably present in a combined amount of about 0.5 to about 40 percent, weight per weight …" In the following paragraph, Friedman states that the "ratio of essential oil to herbal extract in the tablet is in the range of from about 1:4 to about 1:30." (Friedman page 6, lines 10-11). Friedman distinguishes herbal extracts from essential oils and provides examples thereof at page 3, line 2 – 34. Thus the maximum amount of essential oil in a tablet according to Friedman is $1/5^{th}$ of 40%, or 8 wt. %. This is considerably lower than "essential oils representing approximately 25 wt. % to 49.5 wt. % of the lozenge," as specified in amended claim 1.

The Examiner admits in the Office Action that neither Lin nor Gohlke discloses a soft lozenge with an essential oil.

Applicants also note that none of the cited references (Friedman, Lin or Gohlke) has been alleged by the Examiner to disclose the limitation "wherein the micronized ethylcellulose and the flavoring agent are admixed and present in the dosage form at a weight ratio of approximately 1:1.5 to 1.5:1," as specified in independent claims 1 and 109.

Further, the weight percentage (25 – 49.5%) or the weight ratio (1:1.5 to 1.5:1) of essential oil in the claimed dosage form represents an amount of essential oil that is much higher than that taught by Friedman. Sudden oral delivery of such large amount of essential oil by the method of Gohlke (bolus delivered by chewable lozenge) or Lin (pulsatile delivery using a delayed release lozenge) would result in undesirable effects on the user, which is avoided by the claimed dosage form which "gradually releas[es] the flavoring agent over an extended time period in the range of about 15 minutes to about 4 hours."

Since, Friedman, Lin and Gohlke, individually or in combination, do not teach or suggest each and every limitation of independent claim 1, as amended, Applicants submit that a *prima facie* case for obviousness has not been made. Withdrawal of this ground for rejection is respectfully requested.

(ii) Claims 29 and 101 stand rejected under 35 USC 103(a) as being obvious under 35 USC 103(a) over Friedman *et al.* (WO 99/06030) in view of Lin *et al.* (J. Controlled Release 2001) and Gohlke (US 2002/0054917) and further in view of Ventouras (US 6,183,775)

Claims 29 and 101, which set forth a Markush group of possible sweeteners and xylitol, repectively, to be incorporated into the claimed composition, stand separately rejected over Friedman, Lin, and Gohlke, as above, further in view of Ventouras. Ventouras has been cited as describing a controlled release lozenge that can contain xylitol, mannitol, and sorbitol. Ventouras is not otherwise relevant and does not teach or suggest limitations of these claims, which are missing in Friedman, Lin, and Gohlke as discussed above.

Therefore, withdrawal of this ground for rejection is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

The Commissioner is hereby authorized to charge any underpayments or credit any over payments in connection with this communication, including any fees for extension of time, which may be required, to Deposit Account No. 50-5132, referencing Attorney Docket No. BEN-00120US. However, an issue fee may not be charged to this account. The Examiner is invited to call the undersigned if such action might expedite the prosecution of this application.

Respectfully submitted,

Dated: November 3, 2010

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